



paksel
PAKSEL KİMYA
SANAYİ VE TİCARET A.Ş.

HEAD OFFICE: MALTEPE MH. ESKİ ÇIRPICI YOLU SK. MERTER İŞ MERKEZİ
NO: 2 KAT: 10 D: 61-62 ZEYTİNBURNU – İSTANBUL – TURKEY
FACTORY: ÇERKEZKÖY OSB, KARAAĞAÇ MAH. ATATÜRK CAD. 7. SOK. NO: 9-11
KAPAKLI – TEKİRDAĞ – TURKEY

**PRODUCTION AND DISTRIBUTION OF ADULT
DIAPERS AND BED SHEETS**

with a scope of

EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

"7.5.3" "7.5.4" "7.5.5" "7.5.7" "7.5.9.2"

Certificate No : M 9752
Initial Certification Date : 03 March 2014
Certification Date : 07 February 2020
Expiration Date : 06 February 2023

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
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info@kiwa.com.tr

www.kiwa.com.tr

Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.

General Manager



TÜRKAK BDS NO
YS-44D5-5A51



CERTIFICATE

paksel
PAKSEL KİMYA
SANAYİ VE TİCARET A.Ş.

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NO: 2 KAT: 10 D: 61-62 ZEYTİNBURNU – İSTANBUL – TURKEY
FACTORY: ÇERKEZKÖY OSB, KARAAĞAÇ MAH. ATATÜRK CAD. 7. SOK. NO: 9-11
KAPAKLI – TEKİRDAĞ – TURKEY

with a scope of

**PRODUCTION AND SALES OF BABY DIAPERS, HYGIENIC LADY NAPKINS,
ADULT DIAPERS, BED SHEETS AND WET WIPES**

ISO 9001:2015

Has established a quality management system in accordance
with international standard.

“ Following elements of the standard are excluded “

“ None “

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TÜRKAK BDS NO
YS-C081-19FF



EC DECLARATION OF CONFORMITY
ACCORDING TO EC MEDICAL DEVICE DIRECTIVE
REGULATION (EU) 2017/745, ANNEX IV

We herewith declare,

That the following described product in our delivered version complies with the appropriate basic safety and health requirements of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL based on its design and type, as brought into circulation by us.

Company Name : Paksel Kimya San. ve Tic. A.Ş.

GMDN Code : 11239

Company Address : Head Office : Maltepe Mah. Eski Cırpıcı Yolu Sk.
Merter İş Merkezi N.2 K.10 D. 61-62
Zeytinburnu İSTANBUL

Plant: Ç.O.S.B Atatürk Cad. 7. Sok. No:9-11 Çerkezköy
TEKİRDAĞ

Company Telephone : +90 212 481 55 46
+90 282 758 18 58

Company Fax : +90 212 481 55 49
+90 282 758 18 61

Description of the Devices : Adult Diaper

Brand : Selped Extra Dry

Size : Medium , Large

UDI-DI : 8690879712313G3 – Medium
8690879712320FY – Large

Applicable EC Directives : (EU) 2017/745 Medical Devices Directive

Classification : Class I, Rule 1

Issue Date : 08.12.2022

Authorized Signature : Mrs. Muazzez KORKMAZ

Title of Signatory : Responsible


Paksel Kimya Sanayi ve Ticaret
Anonim Şirketi
Marmara Kurumları V.B: 719 003 4918

TECHNICAL DATA SHEETName of Product: **SELPED EXTRA DRY**

SIZES	MEDIUM	LARGE	X-LARGE
Width (mm)	670	760	760
Length (mm)	820	880	960
Pad Length (mm)	680	690	700
Side Tape (length) (mm)	30	30	30
ADL Length (mm)	680	690	700
Pad Weight (gr)	74	82	90
Max. Absorbtion Capacity (g)	1250	1280	1430
ISO 11948-1 Absorbtion Capacity (g)	1900	2000	2050

RAW MATERIALS	CHEMICAL NAME
Nonwoven	Hydrophilic Polypropylene
Leg Cuffs	Hydrophobic Polypropylene
Acquisition Layer	Hydrophilic Polypropylene
Cellulose Pulp	Polysaccharide
SAP	Superabsorbers
Clothlike Backsheet	Polyethylene -Hydrophilic Polypropylene
Velcro Side Tapes	Polyolefin
Elastic Gather	Spandex
Elastic Cuff	Spandex
Hotmelt Adhesive Construction	Modified copolymer rubber
Hotmelt Adhesive Reinforcement	Modified copolymer rubber
Wetness Indication	Holtmelt

MICROBIOLOGICAL ANALYSIS RESULT	
NAME OF MICROORGANISM	RESULTS
Aerobic Mesophilic Bacteria	(-) Not Found
Aspergillus Niger	(-) Not Found
Staphylococcus Aureus	(-) Not Found
Yeast and Moulds	(-) Not Found
Pseudomonas Aeruginosa	(-) Not Found
E.Coli and Coliforms	(-) Not Found
Total Plate Count	(-) Not Found
Candida Albicans	(-) Not Found